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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/354,478	07/15/1999	THOMAS D. TAGGART	STEU-2661	5211

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EXAMINER	
MCKANE, ELIZABETH L	
ART UNIT	PAPER NUMBER
1744	18

DATE MAILED: 03/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/354,478	Applicant(s) TAGGART ET AL.	
	Examiner Leigh McKane	Art Unit 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,7,10-14,16,17 and 20-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,7,10-14,16,17 and 20-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-4, 6, 7, 11-14, 16, 17, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Müller et al (U.S. Patent No. 4,742,667) in view of Kelbrick et al (U.S. Patent No. 5,534,222) and Kümmerer (U.S. Patent No. 4,936,486).

With respect to claims 1, 2, 4, 7, 11, 12, 14, 17, and 21, Müller et al teaches a method and apparatus for sterilizing containers. The invention of Müller et al includes a source of compressed air **11**, a source of sterilant (hydrogen peroxide) **7** with a metering device **8**, an atomizing system **51** for producing an atomized sterilant from the mixing of the sterile air with the sterilant, and a heat source **53** for heating the atomized sterilant, thereby producing a vaporized sterilant, a mechanism (exit of tube **52**) for applying the atomized sterilant to the container **1**, and a supply **14,16** of hot air. Müller et al fails to teach that the source of compressed air is sterile, that the heat source is a source of heated air that is mixed with the atomized sterilant, or that the metering device is a spoon dipper apparatus.

Kelbrick et al teaches a similar method of sterilizing an enclosure using vaporized hydrogen peroxide and hot air for drying. HEPA filter assemblies **54** are used to provide sterile air for drying and vapor transmission. In addition, the source of air is aseptic and filtered (col.4, lines 21-24). It would have been obvious to one of ordinary skill in the art to provide sterile air in the method and apparatus of Müller et al in order to avoid recontamination of the sterilized

containers. Kelbrick et al further discloses mixing sterile air **81** with a sterilant **73** to produce an atomized sterilant and then mixing the atomized sterilant with a continuous source of hot air at **52** to produce a vaporized sterilant. See Figure 4 and col.4, lines 16-50. The heat exchanger is controlled to control air temperature and intrinsically, humidity. As the hot air of Kelbrick et al is a suitable source of heat for vaporizing an atomized hydrogen peroxide sterilant, it would have been obvious to one of ordinary skill in the art to either substitute the heat source of Kelbrick et al for that of Müller et al or to use it *in addition to* the heat source of Müller et al.

Kümmerer discloses a method and apparatus for sterilizing containers with atomized hydrogen peroxide. The source of sterilant incorporates a metering device which uses a spoon dipper apparatus **29**. See col.5, lines 1-3. As the metering device disclosed by Kümmerer is disclosed to be effective in dosing predetermined and variable quantities of a sterilant to a vaporization device, it would have been an obvious choice for the metering device of Müller et al.

As to claims 3 and 13, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

With respect to claims 6 and 16, although not specifically disclosed, the nozzles of Müller et al and Kelbrick et al both appear to be venturi nozzles. Regardless, the use of a well-known type of nozzle for mixing two fluids is not deemed to be patentable in the above combination.

3. Claims 10, 20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Müller et al, Kelbrick et al, and Kümmerer as applied to claims 1, 11, and 21 above, and further in view of Caudill (U.S. Patent No. 5,007,232).

Although Müller et al teaches that the "film of condensate is completely eliminated as the package travels" (col.6, lines 48-50), there is no disclosure of the residual concentration of hydrogen peroxide. Caudill discloses the sterilization of containers with hydrogen peroxide wherein heat is used to evaporate condensed hydrogen peroxide to a residual level of less than 0.5 ppm. See col.8, lines 1-8. As achieving a very low residual level of hydrogen peroxide is important in the sterilization of food containers, it would have been obvious in the method and apparatus of Müller et al.

4. Applicant's arguments filed 1/9/2003 have been fully considered but they are not persuasive.

5. In Applicant's remarks, it is argued that "[n]owhere is there disclosed, or suggested, applying hot sterile air to the atomized sterilant, or a structural equivalent in Müller." The Examiner respectfully disagrees, as Müller et al does indeed teach a structural equivalent. In fact, Müller et al teaches a source of heat **5** which converts the atomized sterilant into a vapor. The resulting combination of Müller et al with Kelbrick et al merely substitutes one source of heat (continuous hot air flowing through pipe **52** of Kelbrick et al) for another (heater **5** of Müller et al). As both patents are directed to sterilization using vapor phase hydrogen peroxide produced from an atomized liquid source of hydrogen peroxide, they are analogous and combinable.

6. Applicant further argues that the hot air of Kelbrick et al is not "continuous" and is only mixed with the atomized sterilant during the sterilization procedure. This is true – but the definition of "continuous" as applied to the sterilization claims at hand only requires that the air flow *not be intermittent* during the sterilization process. Does the sterile air flow of the instant invention remain ON forever? Is applicant alleging that it NEVER turns OFF, at any time?

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 703-305-3387. The examiner can normally be reached on Monday-Wednesday (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Leigh McKane

Leigh McKane
Primary Examiner
Art Unit 1744

elm
March 11, 2003